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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,521	08/09/2000	Katherine Galvin	MNI-094	5630

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EXAMINER
QIAN, CELINE X

ART UNIT	PAPER NUMBER
1636	17

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/635,521	Applicant(s) GALVIN ET AL.	
	Examiner Celine X Qian	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-30 and 70-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-30 and 70-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 March 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 25-30 and 70-78 are pending in the application.

This Office Action is in response to the Amendment filed on 11/14/02.

Response to Amendment

The objection to the specification has been withdrawn in light of Applicants' amendment.

Claims 25-30 and newly added claims 70-78 stand rejected under 35 U.S.C.101 for reasons set forth in the Office Action mailed on 2/28/02 and further discussed below.

Claims 25-30 and newly added claims 70-78 stand rejected under 35 U.S.C.112 1st paragraph for reasons set forth in the Office Action mailed on 2/28/02 and further discussed below.

Claims 25-30 and newly added claims 70-78 stand rejected under 35 U.S.C.112 2nd paragraph for reasons set forth in the Office Action mailed on 2/28/02 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-30 and 70-78 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

In response to the utility rejection, Applicants argue that the claimed invention has specific utility because the specification has shown that GPCR 4941 is overexpressed in a number of tumor samples and cardiovascular tissues, therefore, the compound modulating GPCR

4941 expression would have a specific utility of treating cardiovascular and tumorigenic disorder. Applicants further argue that the asserted utility is substantial because treating cancer and atherosclerosis is a desirable outcome based on the need in art, thus has real world use. Moreover, Applicants argue that the utility is credible because the established correlation between GPCR 4941 expression and tumor samples and cardiovascular tissues. Applicants further compare the claimed invention to the example used in *revised interim utility guideline training material*, and conclude that the invention has well established utility.

Applicants' arguments have been fully considered but deemed unpersuasive. The claimed invention lack utility for same reasons set forth of the record mailed on 2/28/02. Although the specification discloses a correlation between GPCR 4941 expression and tumor samples and cardiovascular tissues, the specification at most establishes the utility of the GPCR 4941 molecule. The example Applicants referred to is different from the current situation. In the example, the claims are directed to a method of assay materials that bind to receptor A and antibody of receptor A, both of which are for diagnostic purpose. The claimed invention is directed to a method of identifying GPCR 4941 modulator that capable of treating cancer and cardiovascular disorder. The specification does not demonstrate a causal relationship between GPCR 4941 overexpression and tumorigenic or cardiovascular disorder. As such, the nexus between modulating GPCR 4941 expression or activity and treating cardiovascular and tumorigenic disorder is missing. The specification does not disclose any other utility for the modulators of GPCR 4941. Therefore, the utility of the GPCR 4941 modulators are not established. Consequently, there is no specific, substantial and credible utility for the method of identifying such modulators. The rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-30 and 70-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to the 112 1st paragraph rejection, Applicants argue that the specification teaches a number of methods of screening compounds for the ability to modulate GPCR4941 activity; hence, the specification has provided ample guidance as to how one skill in the art would use the claimed invention.

Applicants' argument has been fully considered but deemed unpersuasive.

The reasons for the non-enablement rejection were discussed in detail in the previous office action mailed on 2/28/02. Although the specification teaches a number of methods to screen for compounds that modulates GPCR 4941 activity, it does not provide any support for what kind of disorders are caused by aberrant GPCR 4941 expression or polypeptide activity. Mere demonstration of upregulation of GPCR 4941 expression in tumor or angiogenic tissue does not prove the causal relationship between GPCR 4941 expression and the disease state. As such, the nexus between aberrant expression of GPCR 4941 and cardiovascular disorder or tumorigenic disorder is missing. Whether the compounds capable of modulating GPCR 4941

can treat such disorders is unpredictable. Therefore, the claims are not enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-30 and 70-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response to the 112 2nd paragraph rejection with regard to the term "GPCR 4941," Applicants state that this term encompasses a family of GPCR 4941 molecules including allelic variants, homologues, and orthologues of the human GPCR 4941 shown in Figure 1.

The above argument has been fully considered. However, this explanation of the term does not overcome the rejection of the record because the specification fails to describe or define any allelic variants, homologues and orthologues of the human GPCR 4941. It is unclear what percentage homology a nucleic acid or polypeptide must share with the human GPCR 4941 to be considered as an allelic variant, homologue, and orthologue. As such, the metes and bounds of the claim cannot be established. Therefore, the rejection is maintained.

In response to the 112 2nd paragraph rejection with regard to missing method steps, Applicants argue that since the specification has shown that GPCR 4941 is expressed in cardiovascular and tumorigenic disorders, the compounds that modulates GPCR 4941 expression or activity will be useful as therapeutic agents to disorders characterized by GPCR 4941 overexpression. Applicants conclude that "assaying the ability of the compound to modulate

GPCR 4941" is sufficient to identify a compound capable of treating a cardiovascular and tumorigenic disorder.

The above argument has been fully considered but deemed unpersuasive. The specification merely demonstrates a correlation between expression of GPCR 4941 and some tumor cells and cardiovascular tissues. The specification does not provide any evidence whether this is a causal relationship. As such, the nexus between modulating GPCR 4941 expression or activity and treating cardiovascular or tumorigenic disorder is missing. Therefore, the claimed methods lack the step of how to determine whether the GPCR 4941 modulating compound is capable of treating cardiovascular or tumorigenic disorder. The rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
May 30, 2003

REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600